

Russ Vought, Executive Director





www.house.gov/pence/rsc

Ph (202) 226-9717 / fax (202) 226-1633

Legislative Bulletin.....January 10, 2007

Contents:

H.R. 3 — Stem Cell Research Enhancement Act of 2007

Summary of the Bills Under Consideration Today:

Total Number of New Government Programs: 1

Total Cost of Discretionary Authorizations: unknown

Effect on Revenue: \$0

Total Change in Mandatory Spending: \$0

Total New State & Local Government Mandates: 0

Total New Private Sector Mandates: 0

Number of *Bills* Without Committee Reports: 1

Number of *Reported* Bills that Don't Cite Specific Clauses of Constitutional Authority: 0

H.R. 3 — Stem Cell Research Enhancement Act of 2007 – as introduced (DeGette, D-CO)

Order of Business: The bill is scheduled to be considered on Thursday, January 11, pursuant to H.Res. 6 (Title 5, Sec. 509), a rule that the House passed last week closing the bill to amendments, waiving all points of order against the bill and its consideration, deeming the previous question as ordered, providing for three total hours of debate, and providing for one motion to recommit with instructions. (Note: H.Res. 6 was the resolution changing House Rules for the 110th Congress. It also provided for the consideration of several portions of the Democrats' 100-Hour Agenda.) In other words, this bill will come to the floor under a closed rule and without the applicability of any of the new House rules that the Democrats have implemented.

Note: It is unclear what the motion to recommit will entail. More information will be forthcoming as it becomes available.

Background: In the 109th Congress, a bill identical to H.R. 3 (H.R. 810, the Stem Cell Research and Enhancement Act), passed in the House by a vote of 238-194 (Roll Call 204) on May 24, 2005, and passed the Senate by a vote of 63-37 (Roll Call 206) on July 18, 2006. H.R. 810 was vetoed by President Bush on July 19, 2006 (his first and only presidential veto to-date). The same day, the House failed to override the President's veto by a vote of 235-193 (Roll Call 388). A two-thirds vote is required to override a presidential veto, thus the bill failed to receive the required 286 votes and was defeated with a 51-vote margin.

<u>Summary</u>: H.R. 3 creates a new provision in the Public Health Service Act (42 U.S.C. 289 et seq.) requiring the Secretary of HHS to "conduct and support research that utilizes human embryonic stem cells ..." The bill defines as eligible for federal funding human embryonic stem cells that:

- > were derived from human embryos that have been donated from in vitro fertilization clinics, were created for the purposes of fertility treatment, and were in excess of the clinical need of the individuals seeking such treatment;
- it was determined would never be implanted in a woman and would otherwise be discarded; and
- > were donated with written informed consent and without receiving any financial or other inducements to make the donation.

The bill requires final guidelines from NIH within 60 days of enactment and an annual report from the HHS Secretary describing the research conducted.

Additional Information: It is legal in the United States to destroy and conduct research on living and dead human embryos with non-federal funds. It is also legal in the U.S. to conduct research with federal funds on stem cell lines from embryos destroyed prior to September 9, 2001. This bill would require the federal funding of research using viable human embryos, which is currently prohibited under federal law and the President's stem cell policy.

REVERSAL OF CONGRESSIONAL FUNDING BAN AND PRESIDENT BUSH'S POLICY

President's Policy:

H.R. 3 will reverse President George W. Bush's federal stem cell policy announced in an address to the nation on August 9, 2001. In that address, the President stated that **no federal funds** will be used for:

"the derivation or use of stem cell lines derived from newly destroyed embryos;

"the creation of any human embryos for research purposes; or

"the cloning of human embryos for any purpose."

The President's policy did allow federal funds to be used for stem cell lines that had come from embryos already destroyed prior to August 9, 2001. At the time, the President stated, "The embryos from which the existing stem cell lines were created have already been destroyed and no longer have the possibility of further development as human beings." The President stated his policy permits federal funding of research using the more than 60 existing stem cell lines that have already been derived, but will not sanction

or encourage the destruction of additional human embryos. He said in his address, "This allows us to explore the promise and potential of stem cell research without crossing a fundamental moral line by providing taxpayer funding that would sanction or encourage further destruction of human embryos that have at least the potential for life."

Source: http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html.

To see a list of those stem cell lines that are *currently* eligible for federal funding, please visit: http://stemcells.nih.gov/research/registry/eligibilityCriteria.asp.

Congressional Funding Ban:

Since fiscal year 1996, Congress has included in the Labor, HHS and Education Appropriations bill a rider that has been signed into law, which states the following:

SEC. 509.

- (a) None of the funds made available in this Act may be used for
 - (1) the creation of a human embryo or embryos for research purposes; or
 - (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).
- (b) For purposes of this section, the term human embryo or embryos includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells. (emphasis added)

 Source: Section 509 of the FY05 Omnibus Appropriations Act (H.R. 4818)

[Explanation of cross-references: 45 CFR 46 is the part of the Code of Federal Regulations that contains protections for human subjects in federally funded research. 45 CFR 46.208(a)(2) requires that unless an experiment involving a human fetus is designed to benefit that particular child, it cannot involve anything greater than a minimal risk of harm (defined as a risk comparable to that involved in routine examinations or the activities of everyday life). These federal regulation protections cover all human embryos from implantation in the womb until birth; the appropriations rider on human embryo research (Sec. 510 above) covers all other human embryos (those not implanted in the womb).

The Public Health Service Act (42 USC 289g (b)) requires that in assessing allowable risk, a child intended for abortion must be protected as fully from harmful research as the child intended for live birth. The argument that an embryo or fetus is unwanted or would be destroyed anyway cannot be used to justify harmful experimentation at taxpayers expense.]

THE HUMAN EMBRYOS AVAILABLE FOR RESEARCH UNDER H.R. 3:

H.R. 3 will allow federal funds for the destruction of and research on human embryos from in vitro fertilization (IVF) clinics.

The in vitro fertilization process involves combining an egg with sperm to create a human embryo. At this stage, clinics are able to determine whether or not the human embryos have the

genetic makeup of a male or of a female. According to IVF clinics, a human embryo that is "graded" as a "quality" embryo is then implanted into a woman's womb (often more than one at a time) to try and achieve implantation and a full-term pregnancy. Those human embryos graded as "abnormal" are "discarded," according to various clinics.

(See: http://www.advancedfertility.com/embryoquality.htm).

Those human embryos deemed "quality" human embryos that are not implanted into the womb are then usually frozen in a controlled-rate freezer and immersed and stored in liquid nitrogen in a tank (at -196 degrees Centigrade), in a process called Cyroproservation (to see a photo of a human embryo storage freezer, please visit: http://www.advancedfertility.com/cryotank.htm).

The frozen human embryos can be stored for many years and can be defrosted to be implanted into a woman's womb. Some parents place their unused frozen human embryos through an official adoption process with other couples (see:

http://www.nightlight.org/snowflakes_description.asp and Congressional testimony:
http://www.stemcellresearch.org/testimony/strege.htm
htmose commonly, parents allow the IVF clinic to offer their unused frozen human embryos to other infertile female patients through the clinic (see: http://embryodonation.org/downloads/pdf/DonationConsentGeneric.pdf).

The Number of Human Embryos Eligible for Destruction and Research Under H.R. 3:

Many of the human embryos do not survive the freezing and defrosting process. A group of RAND researchers estimated that only 65% of the human embryos survive the freeze-and-thaw process.

The most comprehensive study of the number of human embryos currently in existence at IVF clinics was done by the non-profit research organization RAND. In 2003, RAND released a study that found that as of April 11, 2002, nearly 400,000 human embryos have been "frozen and stored since the late 1970s."

Of the 400,000, 2.8% (11,000 total) have been made available by their parents for research, while the "vast majority of frozen [human] embryos are designated for future attempts at pregnancy."

The vast majority of stored human embryos, 88.2%, are being held for "family building;" 2.3% are awaiting donation to another patient (for implantation in her womb); and 4.5% are held in storage for other reasons, including lost contact with a patient, patient death, abandonment, and divorce.

The RAND researchers noted that based on current, non-federally funded research results, if all 11,000 embryos were used to create embryonic stem cell lines (the cell culture lines federal funds would be used for under H.R. 3), "about 275 embryonic stem cell lines could be created" and that "the actual number is likely to be much lower." The University of Wisconsin used 18 human embryos (that were grown for five days from the date of their conception before being destroyed) to create five embryonic stem cell *lines*. The Jones Institute used 40 embryos of the same age, to create only three stem cell *lines*.

Source: How Many Frozen Human Embryos Are Available for Research? RAND Law &

NO TREATMENTS TO DATE FOR HUMANS OR ANIMALS FROM EMBRYO STEM CELL RESEARCH:

As of January 2007, <u>no animals or human patients have been successfully treated</u> with human embryonic stem cells (see: http://www.stemcellresearch.org/facts/treatments.htm).

H.R. 3 AND HUMAN CLONING:

Because the bill overrides current law, if a human embryo clone was created by an in vitro fertilization clinic for fertility purposes, H.R. 3 would allow federal funds for research on the human clone embryo. Opponents of H.R. 3 have noted that most of the organizations most actively promoting H.R. 3, such as the Biotechnology Industry Organization and the Coalition for the Advancement of Medical Research, are also strong supporters of a certain type of cloning they call therapeutic cloning. Senator Orrin Hatch, the sponsor of a pro-human cloning bill, referred to H.R. 3 as a critical first step, an apparent reference to a pro-cloning bill being the next step.

For several other resources on embryonic stem cell research, and recent breakthroughs on non-embryonic stem cell research, please visit the RSC Website at: http://www.house.gov/pence/rsc/lifeissues_abortion.shtml.

<u>Committee Action</u>: The bill was introduced on January 5, 2007, and referred to the House Committee on Energy and Commerce, which took no official action.

<u>Cost to Taxpayers</u>: A CBO cost estimate is unavailable. According to news reports, in FY04 NIH spent \$24.6 million funding the research allowed on cell lines created from cells removed from human embryos prior to August 2001. **H.R. 3 requires federal funding of human embryo research regardless of the date on which the stem cells were derived from a human embryo, which would likely lead to millions of dollars in additional federal spending.**

<u>Constitutional Authority</u>: An Energy and Commerce Committee report citing constitutional authority is unavailable.

<u>Administration Position</u>: The Administration is opposed to passage of H.R. 3 but has not released an updated Statement of Administration Policy (SAP) as of press time. However, the Administration released a SAP on H.R. 810 on May 24, 2005, which stated:

"The Administration strongly opposes House passage of H.R. 810, which would require Federal taxpayer dollars to be used to encourage the ongoing destruction of nascent human life. The bill would compel all American taxpayers to pay for research that relies on the intentional destruction of human embryos for the derivation of stem cells, overturning the President's policy that supports research without promoting such ongoing destruction. If H.R. 810 were presented to the President, he would veto the bill."

To read the full SAP, please visit:

http://www.whitehouse.gov/omb/legislative/sap/109-1/hr810sap-h.pdf.

<u>Outside Organizations</u>: The following is a partial list of outside organizations opposing H.R. 3 (note: groups that scored the original House vote last year and are likely to score it again are noted with an asterisk):

National Right to Life Committee* US Conference of Catholic Bishops Family Research Council* Christian Coalition* Concerned Women for America* Focus on the Family Christian Medical Association Eagle Forum* **Traditional Values Coalition** Southern Baptist Convention Susan B. Anthony List Republican National Committee for Life Cornerstone Policy Research Culture of Life Foundation Religious Freedom Coalition Coral Ridge Ministries Center For Reclaiming America

<u>Does the Bill Create New Federal Programs or Rules?</u>: Yes. The bill would override current federal funding bans and the President's current administrative policy to require the HHS Secretary to fund human embryonic research, including research on currently living human embryos stored in freezers at IVF clinics.

<u>Does the Bill Contain Any New State-Government, Local-Government, or Private-Sector Mandates?</u>: No.

RSC Staff Contact: Derek V. Baker; derek.baker@mail.house.gov; 202-226-8585

###